6.03 **Medical Evaluation Requirements/Clients Under 18 Years of Age**

(1) Medical evaluation requirements

(a) General - a hearing aid dispenser shall not sell a hearing aid unless the prospective user has presented to the hearing aid dispenser a written statement signed by a licensed physician that states that the patient's hearing loss has been medically evaluated and the patient may be considered a candidate for a hearing aid. The medical evaluation must have taken place within the preceding 6 months.

(b) Waiver to the medical evaluation requirements - If the prospective hearing aid user is 18 years of age or older, the hearing aid dispenser may afford the prospective user an opportunity to waive the medical evaluation requirement of paragraph (1)(a) of this section provided that the hearing aid dispenser: (i) Informs the prospective user that the exercise of the waiver is not in the user's best health interest; (ii) Does not in any way actively encourage the prospective user to waive such a medical evaluation; and (iii) Affords the prospective user the opportunity to sign the following statement: "I have been advised by -------- -------- (Hearing aid dispenser's name) that the Food and Drug Administration has determined that my best health interest would be served if I had a medical evaluation by a licensed physician (preferably a physician who specializes in diseases of the ear) before purchasing a hearing aid. I do not wish a medical evaluation before purchasing a hearing aid."

(2) Clients under 18 years of age - A registrant or apprentice shall not sell a hearing instrument to a person under eighteen (18) years of age unless the client, a parent, or guardian has presented to the registrant or apprentice a written statement signed by a licensed physician that states that the patient's hearing loss has been medically evaluated and the patient may be considered a candidate for a hearing instrument. The physician's evaluation must have taken place within the preceding six months.

(3) If, upon inspection of the ear canal during a hearing aid fitting and upon questioning of the client, there is recent history of infection, any observable anomaly, deformity of ear, unilateral loss of hearing within 90 days, bilateral loss of hearing within ninety (90) days, evidence of cerumen or other occlusion, pain in the ear, discharge, ear bone gap at 15 Db at 500 hz, 1000 hz, and 2000 hz or dizziness, the client shall be instructed to see a physician (preferably a physician who specializes in diseases of the ear). A hearing aid shall not be fitted until medical clearance is obtained for the condition noted or a waiver of informed consent for the specific condition noted or complained of is signed by the client. If, upon the client's return, the condition noted is no longer observable and the client signs a medical waiver, a hearing aid may be fitted.

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Section 6.09: Label and Labeling Requirements/ Requirements Regarding the User Instructional Brochure

(1) Label requirements for hearing aids
Hearing aids shall be clearly and permanently marked with: (a) The name of the manufacturer or distributor, the model name or number, the serial number, and the year of manufacture. (b) A ``+" symbol to indicate the positive connection for battery insertion, unless it is physically impossible to insert the battery in the reversed position.
labeling information required by this section shall be included in a User Instructional Brochure that shall be developed by the manufacturer or distributor, shall accompany the hearing aid, and shall be provided to the prospective user by the dispenser of the hearing aid in accordance with 265 CMR 6.09 (2) and (3).

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(2) Availability of User Instructional Brochure
Upon request by an individual who is considering purchase of a hearing aid, a dispenser shall, with respect to any hearing aid that he dispenses, provide a copy of the User Instructional Brochure for the hearing aid or the name and address of the manufacturer or distributor from whom a User Instructional Brochure for the hearing aid may be obtained. In addition to assuring that a User Instructional Brochure accompanies each hearing aid, a manufacturer or distributor shall with respect to any hearing aid that he manufactures or distributes: Provide sufficient copies of the User Instructional Brochure to sellers for distribution to users and prospective users; and Provide a copy of the User Instructional Brochure to any hearing aid professional, user, or prospective user who requests a copy in writing.

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(3) Opportunity to Review User Instructional Brochure
Before signing any statement and before the sale of a hearing aid to a prospective user, the hearing aid dispenser shall: (1) Provide the prospective user a copy of the User Instructional Brochure for a hearing aid that has been, or may be selected for the prospective user; (2) Review the content of the User Instructional Brochure with the prospective user orally, or in the predominate method of communication used during the sale; (3) Afford the prospective user an opportunity to read the User Instructional Brochure.

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(4) Warning statement
The User Instructional Brochure shall contain the following warning statement: Warning to Hearing Aid Dispensers A hearing aid dispenser should advise a prospective hearing aid user to consult promptly with a licensed physician (preferably an ear specialist) before dispensing a hearing aid if the hearing aid dispenser determines through inquiry, actual observation, or review of any other available information concerning the prospective user, that the prospective user has any of the following conditions: (i) Visible congenital or traumatic deformity of the ear. (ii) History of active drainage from the ear within the previous 90 days. (iii) History of sudden or rapidly progressive hearing loss within the previous 90 days. (iv) Acute or chronic dizziness. (v) Unilateral hearing loss of sudden or recent onset within the previous 90 days. (vi) Audiometric air-bone gap equal to or greater than 15 decibels at 500 hertz (Hz), 1,000 Hz, and 2,000 Hz. (vii) Visible evidence of significant cerumen accumulation or a foreign body in the ear canal. (viii) Pain or discomfort in the ear.

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Special care should be exercised in selecting and fitting a hearing aid whose maximum sound pressure level exceeds 132 decibels because there may be risk of impairing the remaining hearing of the hearing aid user. (This provision is required only for those hearing aids with a maximum sound pressure capability greater than 132 decibels (dB).)

(5) Notice for prospective hearing aid users.

The User Instructional Brochure shall contain the following notice: Important Notice for Prospective Hearing Aid Users Good health practice requires that a person with a hearing loss have a medical evaluation by a licensed physician (preferably a physician who specializes in diseases of the ear) before purchasing a hearing aid. Licensed physicians who specialize in diseases of the ear are often referred to as otolaryngologists, otologists or otorhinolaryngologists. The purpose of medical evaluation is to assure that all medically treatable conditions that may affect hearing are identified and treated before the hearing aid is purchased. Following the medical evaluation, the physician will give you a written statement that states that your hearing loss has been medically evaluated and that you may be considered a candidate for a hearing aid. The physician will refer you to a hearing aid dispenser for a hearing aid evaluation. The hearing aid dispenser will conduct a hearing aid evaluation to assess your ability to hear with and without a hearing aid. The hearing aid evaluation will enable the dispenser to select and fit a hearing aid to your individual needs. If you have reservations about your ability to adapt to amplification, you should inquire about the availability of a trial-rental or purchase-option program. Many hearing aid dispensers now offer programs that permit you to wear a hearing aid for a period of time for a nominal fee after which you may decide if you want to purchase the hearing aid. Federal law restricts the sale of hearing aids to those individuals who have obtained a medical evaluation from a licensed physician. Federal law permits a fully informed adult to sign a waiver statement declining the medical evaluation for religious or personal beliefs that preclude consultation with a physician. The exercise of such a waiver is not in your best health interest and its use is strongly discouraged. children with hearing loss In addition to seeing a physician for a medical evaluation, a child with a hearing loss should be directed to an audiologist for evaluation and rehabilitation since hearing loss may cause problems in language development and the educational and social growth of a child. An audiologist is qualified by training and experience to assist in the evaluation and rehabilitation of a child with a hearing loss.

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(6) Technical data

Technical data useful in selecting, fitting, and checking the performance of a hearing aid shall be provided in the User Instructional Brochure or in separate labeling that accompanies the device. The determination of technical data values for the hearing aid labeling shall be conducted in accordance with the test procedures of the American National Standard ``Specification of Hearing Aid Characteristics,'' ANSI S3.22-1996 (ASA 70-1996) (Revision of ANSI S3.22-1987). As a minimum, the User Instructional Brochure or such other labeling shall include the appropriate values or information for the following technical data elements as these elements are defined or used in such standard: (i) Saturation output curve (SSPL 90 curve). (ii) Frequency response curve. (iii) Average saturation output (HF-Average SSPL 90). (iv) Average full-on gain (HF-Average full-on gain). (v) Reference test gain. (vi) Frequency range. (vii) Total harmonic

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distortion. (viii) Equivalent input noise. (ix) Battery current drain. (x) Induction coil sensitivity (telephone coil aids only). (xi) Input-output curve (ACG aids only). (xii) Attack and release times (ACG aids only).

(7) Statements in User Instructional Brochure other than those required.
A User Instructional Brochure may contain statements or illustrations in addition to those required by 265 CMR (4), (5) and (6) if the additional statements: (i) Are not false or misleading in any particular, e.g., diminishing the impact of the required statements; and (ii) Are not prohibited by the regulations of the Board of Registration of Hearing Instrument Specialists or the Federal Trade Commission.